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August 20, 2004

INTERNET ADDRESS: JGOLD@SKGF.COM

Art Unit 1644

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 10/690,639; Filed: October 23, 2003

Pharmaceutical Composition of F(ab')₂ Antibody Fragments (As For:

Amended)

Inventors:

de Silanes et al.

Our Ref:

2099.0010001/JAG/LAV

Sir:

Transmitted herewith for appropriate action are the following documents:

- Information Disclosure Statement (3 pp.); 1.
- 2. Form PTO-1449 listing 34 cited documents (6 pp.);
- Copies of 10 cited documents; and 3.
- Return postcard. 4.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents August 20, 2004 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Laura Vogel Laura A. Vogel Reg. No. 55,702 Jorge A. Goldstein

Attorney for Applicants Registration No. 29,021

JAG/LAV/rjv Enclosure

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HE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

de Silanes et al.

Appl. No. 10/690,639

Filed: October 23, 2003

For: Pharmaceutical Composition of

F(ab')₂ Antibody Fragments (As

Amended)

Confirmation No. 9165

Art Unit:

1644

Examiner:

To be assigned

Atty. Docket: 2099.0010001/JAG/LAV

1.

Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents AA1-AG1, AL1, AR2, AR6, AS1, AS2, AS5, AS6, AT1 and AT5 were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/798,076, filed March 5, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d). Copies of documents AH1-AK1 and AA2-AE2 are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 C.F.R. § 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003." A copy of each other document is attached.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language document AL1 cited on Form PTO 1449:

Document AL1, Spanish Patent Publication No. 2 106 183, is in the Spanish language. An English language abstract of document AL1 is cited as document AT5.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being submitted before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

Laura A. Vogel Neg. No. 55,702

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Jorge A. Goldstein

Attorney for Applicants Registration No. 29,021

Date:

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Page 1 of 6 ATTY. DOCKET NO. APPLICATION NO. 2099.0010001/JAG/LAV 10/690,639 **FORM PTO-1449** FIRST NAMED INVENTOR INFORMATION DISCLOSURE STATEMENT Silanes et al. FILING DATE **ART UNIT** October 23, 2003 1644 **U.S. PATENT DOCUMENTS EXAMINER** NAME CLASS **SUB-CLASS** DOCUMENT NUMBER DATE FILING DATE INITIAL AA1 4,806,346 02/21/1989 12/16/1986 Hum et al. AB1 4,814,433 03/21/1989 Fredrickson 09/16/1987 AC1 4,849,352 07/18/1989 Sullivan et al. 10/09/1984 AD1 4,940,670 07/10/1990 Rhodes 04/09/1986 AE1 5,328,834 Ngo et al. 07/12/1994 09/08/1989 AF1 5,733,742 03/31/1998 Landon 03/10/1995 AG1 5,888,511 Skurkovich et al. 03/30/1999 12/23/1996 6,333,032 AH1 12/25/2001 Skurkovich et al. 12/22/1997 Al1 6,534,059 03/18/2003 Skurkovich et al. 01/28/2001 López de Silanes et al. AJ1 6,709,655 03/23/2004 03/05/2001 2003/0215448 11/20/2003 Skurkovich et al. AK1 03/14/2003 FOREIGN PATENT DOCUMENTS **EXAMINER DOCUMENT NUMBER** INITIAL COUNTRY **CLASS** DATE SUB-CLASS TRANSLATION Yes AL1 11/01/1997 2 106 183 Spain X No Yes AM No Yes AN No Yes AO No Yes AP No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Cain, B.S., et al., "The Physiologic Basis for Anticytokine Clinical Trials in the Treatment of AR 1 Sepsis," J. Am. Coll. Surg. 186:337-351, American College of Surgeons (1998) Fekade, D., et al., "Prevention of Jarisch-Herxheimer Reactions by Treatment with AS Antibodies Against Tumor Necrosis Factor a," N. Engl. J. Med. 335:311-315, Massachusetts 1 Medical Society (1996) Fox, D.A., "Cytokine Blockade as a New Strategy to Treat Rheumatoid Arthritis," Arch. Intern. AT 1 Med. 160:437-444, American Medical Association (2000) **EXAMINER**

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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•		ATTY. DOCKET NO.	APPLICATION NO.
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b		ATTY. DOCKET NO.	APPLICATION NO.
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